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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

Docket No. 98N-1038, "Irradiation in the Production, Processing, and Handling of Food"

To Whom It May Concern:

The FDA should retain the current labeling law, the current terminology of "treated with radiation," and use the *radura* symbol on all irradiated whole foods.

Regarding the issue of labeling, in its initial petition, the FDA concluded that irradiation was "a material fact" about the processing of food and, thus, should be disclosed. The material fact remains; therefore, labeling should remain. Consumer acceptability, storage qualities, and nutrients are affected. Some irradiated foods have different texture and spoilage characteristics than untreated foods. Most fruits and vegetables have nutrient losses that are not obvious or expected by the consumer.

*In addition, processing by irradiation causes chemical changes that are not evident and are potentially hazardous. "We know a great deal about the macronutrients (protein, carbohydrate and fat) and the micronutrients (vitamins and minerals). What is far less well-defined is all the other physiologically active components of foods, especially plant foods," says Sheldon Margen and Dale A. Ogar in today's Los Angeles Times. All irradiated foods contain unique radiolytic products that have never been tested. Whether or not the FDA has approved irradiation as safe, it remains a new technology with no long-term human feeding studies. Consumers certainly have the right to know if this process has been used on their food.

As to the kind of label used, I believe that the label should be large enough to be readily visible to the consumer, on the front of the package. For displayed whole foods such as produce, a prominent informational display should be used containing the term "irradiation" and the *radura* symbol. Because of the newness of the technology and the need to assess the public health effects of widespread use of irradiated foods, I believe that the FDA's labeling requirement should not be permitted to expire.

Yours truly,



*copy of article appearing in today's Los Angeles Times at S4 attached.

98N-1038

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Shedding Light on Nutrition's Gray Area

Eating Smart

By SHELDON MARGEN
and DALE A. OGAR

According to our Webster's Unabridged Dictionary, food is "any nourishing substance that is eaten or otherwise taken into the body to sustain life, provide energy, promote growth, etc."

It's interesting to note that the dictionary writers added "etc." to the definition, thereby recognizing we still do not know all the things that food does in, and for, the body.

The incredibly complex relationship between food and health continues to be the focus of intense research in the scientific community. It has also spawned an enormous market for so-called nutritional supplements, functional foods and "nutriceuticals," the popularity of which relates far more to our desire for shortcuts and magic bullets than to any evidence about the effectiveness of these products.

The modern science of nutrition actually dates to the early part of this century. We now know a great deal about the macronutrients (protein, carbohydrate and fat) and the micronutrients (vitamins and minerals). What is far less well-defined is all the other physiologically active components of foods, especially plant foods.

These other substances, known collectively as phytochemicals ("phyto" means "plant" in Greek), don't seem to have any nutritional value in the usual sense—they don't supply vitamins or minerals, and they have no calories.

Some of them are responsible for the colors, smells and tastes of foods. Others are mostly useful to the plant itself by offering protection from the sun's radiation and from insects. About 4,000 phytochemicals have been identified, but fewer than 200 have been extensively investigated for their potential anti-cancer, heart-protective and other beneficial effects.

But despite the lack of solid scientific information about many phytochemicals (especially in humans), the folklore surrounding them is enormous.

Some of the long, complicated names of phytochemicals are already familiar to many health-conscious individuals. For example, indoles found in broccoli, Brussels sprouts and other members of the cabbage family (cruciferous vegetables) have been shown to slow the growth of certain cancers in animals. Protease

Coming
Wednesday in

Food

Salad Season

A low-fat grilled chicken and pasta salad in a roasted pepper dressing with a hint of sour cream.

inhibitors and isoflavones in soybeans likewise appear to protect against cancer in animals.

There are several theories to explain how this happens. It may be that certain phytochemicals keep the cell chemistry stable by serving as antioxidants to mop up free radicals, or they may prevent carcinogens from being formed, or they may stimulate the production of enzymes that actually detoxify the carcinogens. Others may suppress cancer development in cells that have already been exposed to carcinogens, or they might block the action of a carcinogen on a targeted organ or tissue.

Cancer isn't the only disease that may be affected by phytochemicals. Some substances in foods may reduce the risk of coronary artery disease by preventing the oxidation of bad cholesterol, or by reducing the production or absorption of cholesterol, or by affecting blood pressure and clotting.

The major research emphasis in the area of phytochemicals has been to identify which elements in foods may protect against cancer and heart disease, and to concentrate and combine them to produce special so-called "designer foods." Unfortunately, food chemistry is very complicated and alongside the good phytochemicals, there are many that are powerful toxins (like those found in poisonous mushrooms).

So, what does this mean for the average consumer? Should we rush out to buy bottles of flavonol, saponin, indole and carnosol?

Although the subject is complicated, the answer is quite simple. No! All the research about phytochemicals is in its early stages. Isolating one or two substances from a food or a group of foods is not likely to mimic the effect of eating

the whole food, with its full complement of phytochemicals intact. There may be other substances and interactions that we know nothing about. And no one food has all the goodies either. This is the best reason we know to follow that tried and true advice to eat a variety of nutritious fruits, vegetables and grains.

For example, broccoli is an excellent food, but your diet should also include carrots and tomatoes. Apples, oranges and bananas might be your favorite fruits, but you should also include berries, grapefruit and plums. While white potatoes are great, try different kinds of rice and test all the whole grains you can find.

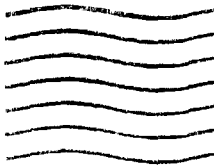
Frozen or canned produce and juices are also excellent sources of nutrients. Some phytochemicals (like some vitamins) can be destroyed by heating or escape into the water, so try not to overcook your foods. Steam or microwave your vegetables when you can.

The following list includes a small sample of phytochemicals with potential anti-cancer and/or heart-protective effects and the foods that contain them.

- Indoles: cruciferous vegetables such as broccoli, cabbage, kale.
- Isothiocyanates (such as sulforaphane): cruciferous vegetables.
- Phytosterols: soybeans, other legumes, cucumbers, other fruits and vegetables.
- Flavonoids: citrus, onions, apples, grapes, wine, tea.
- Isoflavones: soybeans, other legumes, licorice.
- Catechins: tea.
- Ellagic acids: strawberries, raspberries, grapes, apples.
- Anthocyanosides: red, blue, and purple plants such as eggplant, blood oranges, blueberries.
- Allyl sulfides and other organosulfurs: garlic, onions, leeks.
- Saponins: garlic, onions, licorice, legumes.
- Phenolic acids: all plants.
- Protease inhibitors: soybeans and all plants.
- Carotenoids: orange, red, yellow fruits, many green vegetables.
- Monoterpenes: oranges, lemons, grapefruit.
- Capsaicins: chili peppers.
- Lignans: flaxseed, berries, whole grains, licorice.
- Triterpenoids (such as glycyrrhizin): citrus fruit, mushrooms, licorice.

Dr. Sheldon Margen is professor of public health at UC Berkeley; Dale A. Oggar is managing editor of the UC Berkeley Wellness Letter. They are the authors of several books, including "The Wellness Encyclopedia of Food and Nutrition."

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